UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Civil Action No. 05-11805-NMG
v.	:	
RICHARD F. SELDEN,	:	
Defendant.	:	

DEFENDANT RICHARD F. SELDEN'S STATEMENT IN CONNECTION WITH THE SEPTEMBER 28, 2006 STATUS CONFERENCE

In connection with the status conference scheduled before this Court on Thursday, September 28, 2006, defendant Richard F. Selden respectfully submits the following statement regarding the U.S. Food and Drug Administration's ("FDA's") recent statement that it will take the agency 22 months to comply with Dr. Selden's federal subpoenas issued on October 28, 2005 (the "Subpoenas").

Preliminary Statement

On August 16, 2006, U.S. District Judge Ricardo M. Urbina issued an order in S.E.C. v. Selden, Case No. 1:05-mc-00476-RMU (D.D.C.), granting in its entirety Dr. Selden's motion to compel the FDA's compliance with the Subpoenas (the "D.C. Order").[1] However, notwithstanding the pretrial schedule in this action (which, among other things, provides that all written discovery must be completed by October 30, 2006), the FDA has said it will need another 22 months to comply with the Subpoenas.

[1] Dr. Selden submitted a copy of the D.C. Order and related Memorandum Opinion to this Court with his Notice Of Filing Joint Status Report (Docket No. 16, filed Aug. 25, 2006).

Background

This is a securities enforcement action brought against Dr. Richard F. Selden by the U.S. Securities and Exchange Commission ("SEC"). Dr. Selden is the founder and former President and Chief Executive Officer of Transkaryotic Therapies, Inc. ("TKT"), a small biotechnology firm previously located in Cambridge, Massachusetts.[2] The SEC alleges that Dr. Selden violated the federal securities laws in connection with the FDA's review for domestic marketing approval of Replagal, TKT's drug for the treatment of Fabry disease, a rare genetic disorder. According to the Complaint, Dr. Selden, in his position as CEO of TKT, is responsible for a "series of [allegedly] materially misleading public statements by TKT about the status of the FDA application for Replagal." Complaint, SEC v. Selden (filed Sept. 1, 2005) ("Compl."), ¶ 1.

The SEC's entire case is based on the FDA's review of TKT's application for Replagal, its communications with TKT in this regard, and the steps both the FDA and TKT perceived as necessary for Replagal to obtain marketing approval in the United States. See, e.g., Compl. ¶¶ 2-4, 12-14, 21-22, 24-26, 28-33, 35, 38-39, 41-42, 44-53, 55, 59-60, 62, 66, 70 & 74.

Given the critical importance of FDA evidence to Dr. Selden's defense, on October 28, 2005 -- the first day he was permitted to do so by the Federal Rules of Civil Procedure -- Dr. Selden issued two federal subpoenas on the FDA going directly to the issues raised by the SEC's Complaint. The FDA opposed the Subpoenas. That began an eleven-month effort by Dr. Selden to secure his needed FDA discovery. The brief chronology of that effort is as follows:

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[2] In July 2005, TKT was acquired by Shire Pharmaceuticals Group plc, a U.K. corporation.

Chronology

October 2005

- Dr. Selden issued the Subpoenas out of U.S. District Court for the District of Columbia ("D.C. Court"). The FDA first refused to accept service of the Subpoenas, then did so several days later.

November 2005

- The FDA Chief Counsel's Office informed Dr. Selden by letter that it would not comply in any respect with the Subpoenas and requested that they be withdrawn.

- Dr. Selden responded to the FDA's letter, restating the essential nature of the subpoenaed discovery, reviewing the FDA's extensive prior cooperation with the SEC in this case, reviewing the relevant case law, and requesting that the FDA reconsider its position.

- This Court held the Rule 16 scheduling conference. At the conference, counsel for Dr. Selden informed the Court of the Subpoenas and the discovery dispute with the FDA, and advised that the open issue of FDA discovery could impact the scheduling of this action going forward.

- When agreement with the FDA could not be reached, Dr. Selden filed a motion to compel in the D.C. Court. S.E.C. v. Selden, Case No. 1:05-mc-00476-RMU (D.D.C., filed Nov. 23, 2005).

December 2005

- The FDA filed its opposition to Dr. Selden's motion to compel and cross-moved to quash the Subpoenas. Among the FDA's asserted grounds was the position that the FDA is not a "person" under Fed. R. Civ. P. 45 and thus cannot be subpoenaed.

- Dr. Selden filed his opposition to the FDA's motion to quash and reply in further support of his motion to compel.

January 2006

- The FDA filed its reply in further support of its motion to quash.

February 2006

- The D.C. Court issued an order holding the matter in abeyance pending decision by the U.S. Court of Appeals for the District of Columbia Circuit in Yousuf v. Samantar, No. 05-5197 (D.C. Cir.) ("Yousuf"), on the grounds that the enforcement of the federal governmental subpoena

in that case raised some of the same issues raised during the proceedings before the D.C. Court.[3]

- Days later, Dr. Selden moved the U.S. Court of Appeals for leave to file a brief in Yousuf as an amici curia.

- The Department of Justice filed a brief opposing Dr. Selden's motion for leave, and the U.S. Court of Appeals denied Dr. Selden's motion.

- Dr. Selden filed an unopposed motion with this Court seeking to extend all pretrial deadlines by six months in light of the FDA's refusal to comply with the Subpoenas as well as the continuing proceedings in the D.C. Court. (See Docket Nos. 14 & 15.)

March 2006

- This Court granted Dr. Selden's motion to amend the Scheduling Order and set the following revised deadlines, among others:

Sept. 29, 2006:	Last day to serve written discovery
Oct. 30, 2006:	Last day to answer written discovery
Feb. 28, 2007:	Last day for fact depositions
June 30, 2007:	Last day of expert discovery
Aug. 17, 2007:	Last day to file dispositive motions

- In this matter, counsel for the SEC contacted Dr. Selden and offered to assist Dr. Selden in obtaining discovery from the FDA.

- Dr. Selden served "Touhy" requests for testimony on the FDA.[4]

April-May 2006

- At the prompting of the SEC, the FDA began a dialogue with Dr. Selden. Numerous phone calls took place. During this time Dr. Selden agreed to narrow several of his requests.

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[3] A copy of the D.C. Court's February 2006 Order was provided to this Court in connection with Dr. Selden's unopposed motion to extend the Scheduling Order in this matter. (See Docket No. 15, Ex. 1.)

[4] The FDA's Touhy regulations (named after United States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951)), are contained at 21 C.F.R. Part 20, and provide a mechanism for private citizens (whether or not in litigation) to request testimony and documents from the FDA. With respect to documents, Dr. Selden complied with Touhy by serving the subpoenas. Dr. Selden decided to make Touhy requests for testimony in light of the FDA's continued intransigence and the prospect of several more months of delay in obtaining relief in court.

June 2006

- The D.C. Circuit issued its ruling in Yousuf, holding, among other things, that federal governmental agencies (such as the FDA) are "persons" subject to subpoena under Rule 45. Yousuf v. Samantar, 451 F.3d 248, 252-57 (D.C. Cir. 2006).

- Pursuant to the D.C. Court's February 2006 Order, Dr. Selden and the FDA submitted memoranda regarding the impact of the Yousuf decision on their respective motions to compel and to quash the Subpoenas.

July 2006

- More than two months after receiving Dr. Selden's March 2006 Touhy requests, the FDA responded by refusing to produce any of the witnesses requested by Dr. Selden for testimony, but for the witness from whom the SEC had previously taken testimony. The FDA's sole stated rationale for denying the testimony was that the testimony would be "duplicative."

- Dr. Selden responded to the FDA's Touhy letter, pointing out the many respects in which the testimony being sought is not duplicative and requesting that the FDA reconsider its refusal to produce the witnesses for testimony. The FDA has never responded to this letter.

- With respect to documents, the SEC-initiated dialogue between Dr. Selden and the FDA continued; however, despite making progress on the substance, the FDA had yet to produce a single piece of paper.

August 2006

- Judge Urbina granted in its entirety Dr. Selden's motion to compel FDA compliance with the Subpoenas and denied the FDA's motion to quash same. The Court also required the parties to submit a Joint Status Report within fifteen days and to provide a courtesy copy to this Court.

- The Joint Status Report was filed with the D.C. Court and a courtesy copy was provided to this Court. (See Docket No. 16.) Among other things, the FDA stated in the Report that it will take the agency 22 months to review and produce the requested documents. (According to the FDA's estimate, one person working full time will need six-to-seven weeks to review and produce a single box of documents.)

- Given the FDA's 22-month predicted production, and other issues identified in the Joint Status Report, Dr. Selden requested a conference before the D.C. Court. No such conference has yet been scheduled.

As the above clearly demonstrates, Dr. Selden promptly, diligently and aggressively pursued discovery from the FDA in this matter -- by far the most important non-party to his defense -- for nearly eleven months. Still, notwithstanding the D.C. District Court's favorable ruling, Dr. Selden has not come close to obtaining the FDA discovery he has sought since October of 2005.

Conclusion

Consequently, while Dr. Selden continues to pursue substantive relief before the D.C. Court in response to the FDA's positions, he respectfully seeks this Court's guidance on the pretrial schedule so he may mount a fair and complete defense to the SEC's charges.

Dated: September 20, 2006
Boston, Massachusetts

Respectfully submitted,

/s/ Thomas J. Dougherty

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CERTIFICATE OF SERVICE

I, Justin J. Daniels, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on September 20, 2006.

Dated: September 20, 2006

/s/ Justin J. Daniels
Justin J. Daniels